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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
FAN, J

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ART UNIT	PAPER NUMBER
1203	5

DATE MAILED: 03/11/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1-20 are pending in the application.
   Of the above, claims 12, 13 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1-11, 14-20 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

☐ Other

examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Whichever group is elected, further restriction and election of a single species is required because both groups contains claims directed to the numerous patentably distinct species of compounds with distinct structural cores.

During a telephone conversation with Mr. Crowley on March 4, 1992 a provisional election was made with traverse to prosecute the invention of group I, a single disclosed species of claims 8, claims 8-11 and 1-7 and 14-20 the subject matter of claims wherein compounds, composition containing, method of using of the following structure. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1,13 and the subject matter of claims 1-11, 14-20 wherein compounds, composition method not embraced above which is subject to further restriction are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The withdrawn subject matter of claims 1-7, 14-20 is properly restricted because they embrace species that differ materially in structure so that a reference which anticipated but one species (the elected species) would not render obvious other species not embraced by the above indicated generic inventive

concept. In addition, for other species not embraced by the above indicated generic concept, separate search areas would be required in classes 536,544, 548 and the like depending upon the size, structure and number of heterocyclic groups present.

Claims 1-7, 14-20 are rejected as being drawn to improper Markush rejections. Note the above rationale. The deletion of the non-elected subject matter would overcome this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure.

The following reasons apply:

1. Applicants' disclosure constitutes an invention to experiment, that is, the disclosure "present enormous work-loads that would require undue experimentation to find proper operative chemical synthesis, reaction conditions, therapeutic mode of administration, dosage the like.

Further, with respect to the prima facie case of non-enablement, it is noted that a single embodiment may provide broad enablement is cases involving predictable factors, such as

mechanical (In re Myers) or electrical elements. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more is required. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Here, applicants' fail to provide those having ordinary skill in the art reasonable assurance, as by adequate representative examples, that myriad of compounds falling within the scope of the claims can be prepared and used. See In re Surrey, 370 F.2d 349, 151 USPQ 724 (CCPA 1966).

2. The data set forth in the specification relate to in vitro studies of the claimed compounds with respect to their inhibitory effect on specified enzymes. There are no in vivo studies and there is no data in the record which correlates in vitro studies with in vivo utilization and usefulness. There is nothing in the record which establishes that the claimed protease inhibitors are effective to treat AIDS in humans.

3. Enzyme inhibitory effect is very structural, steric, configurational specific. It is very much like lock and key situation. Applicants fails to provide objective evidence to substantiate the myriads of compounds are useful for the allerged utility. Note zeffren reference.

Claims 1-11, 14-20 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-7, 14-20 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following reasons apply:

1. The term "alkyl" "alkoxy" and terms which contain "alkyl", "alkoxy" are beyond the enablement since there is no carbon number limitation.

2. The term "aryl" and any term containing "aryl" reads on multiple rings of twenty or more.

Claims 1-11, 14-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 14-20 of copending application Serial No. 518,730 allowed on February 12, 1992 in view of EP 337,714 of record in the parent file SN 616170, EP 337,714 teaches the interchangeability of -CH-CH wherein R^9 is as various defined.
\ \
OH R^9

This is a *provisional* obviousness-type double patenting rejection.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37

C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Applicants' presentation of prior art statement and accompanying references is noted with appreciation. The references have been placed of record in the file.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

The status of all parent file should be updated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane T. Fan whose telephone number is (703) 308-4705.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

J. T. Fan

JANE T. FAN
PRIMARY EXAMINER
ART UNIT 123

Fan:lb
March 10, 1992